

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO ETHICON WAVE 6 CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE  
CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter “Ethicon”) submit this memorandum in support of their motion to exclude certain opinions of Bruce Rosenzweig, M.D., with respect to the cases set forth in Exhibit A.

In addition to adopting its briefing in the Wave 5 cases (Docs. 4374 (Motion), 4375 (Memorandum in Support), and 4632 (Reply)), Ethicon requests that the Court preclude Dr. Rosenzweig from providing certain unreliable opinions about the TVT Secur device. In this wave of cases, Dr. Rosenzweig has provided certain case-specific opinions about TVT Secur that are unsupported in his general report. Ethicon, therefore, supplements its previous briefing to address those general opinions.

**INTRODUCTION**

Dr. Rosenzweig is a pelvic surgeon and urogynecologist with experience in the surgical treatment of stress urinary incontinence and pelvic organ prolapse, as well as the removal of sling systems. Ex. B, curriculum vitae. He intends to provide general opinions about TVT, TVT-O, TVT-Abbrevio, TVT Exact, TVT Secur, and Prosima. Ex. C-H, Expert Reports. As set forth below and its Wave 5 briefing, the Court should preclude Dr. Rosenzweig from testifying

about matters that are beyond his expertise, that are irrelevant, that are unreliable, that are prejudicial, and/or that would confuse or mislead the jury.

### **LEGAL ARGUMENT**

Ethicon incorporates by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

#### **I. The Court should preclude Dr. Rosenzweig from testifying about certain alleged complications associated with TVT Secur.**

The Court should exclude certain of Dr. Rosenzweig's opinions specific to the TVT Secur device on the basis that they are unreliable. In particular, the Court should exclude Dr. Rosenzweig's general opinions about TVT Secur's fleece tips and about TVT Secur's implanting introducer.

##### **A. Opinions about the device's fleece tips.**

Dr. Rosenzweig suggests that the TVT Secur's absorbable fleece tips, made from ETHISORB®, may have contributed to alleged fixation issues with the device. According to Dr. Rosenzweig, "Ethisorb **may** have also been a contributing factor to the fixation concern (it had never been studied for mesh fixation in the human pelvic floor region)," and removing the "defective fleece tips . . . would have been safer." Ex. G, TVT Secur Gen. Report at 63, 76-77 (emphasis added).

Dr. Rosenzweig cites no support whatsoever for his suggestion that the ETHISORB fleece tips contributed to fixation problems. In fact, he is not even sure himself, as he merely opines that it "may" have been a contributing factor. *Id.* at 63.

His opinion has not been subject to peer review or testing, and he cites no studies related to this issue. Thus, this opinion does not come close to surviving *Daubert* scrutiny and should be excluded.

**B. Opinions about the device's introducer.**

Dr. Rosenzweig also claims that “[e]liminating the sharp introducer” associated with the TVT Secur device “would have been safer.” Ex. G, TVT Secur Gen. Report at 76-77. The Court should also exclude this opinion on the basis that it is unreliable.

As support for his opinion that the introducer is unsafe, Dr. Rosenzweig states as follows in his general report:

One study prepared by Lekha S. Hota, M.D., an Ethicon KOL, stated that “there also was an increased incidence of mesh exposure in the TVT-S group. Although the etiology of this complication is **unclear**, we theorize that the sharper edges of the TVT-S introducer **potentially** create more trauma to the vaginal epithelium and may result in higher erosion rates.” Ethicon never investigated the **possibility** that its product’s sharper edges might subject patients to greater tissue trauma, **potentially** resulting in erosions.

*Id.* at 63-64 (emphasis added; quoting Hota L., “TVT Secur (Hammock) Versus TVT-Obturator,” *Female Pelvic Med. Reconstr. Surgery*, 18(1): 41-45 (2012), filed herewith as Ex. I).

Again, in his own words, Dr. Rosenzweig notes only a “possibility” that merely has been theorized and not subject to any testing or studies. Ethicon explored this opinion with Dr. Rosenzweig during deposition. Ex. J, 2/4/16 Rosenzweig Dep. at 115:8-116:10, 147:19-148:12, 156:3-160:12. Dr. Rosenzweig conceded:

A. They do say they theorize. They do so they theorize, they do state we theorize and potentially create more trauma, but they do document the sharp edges.

\* \* \*

Q. But are you aware if they followed up with additional testing to confirm that hypothesis or theory?

A. **Not that I’m aware of.**

*Id.* at 158:10-13, 160:9-12 (emphasis added).

To be admissible, an expert's opinion must be much more reliable than an educated guess. This opinion again does not pass *Daubert* muster and should be excluded.

### **CONCLUSION**

For the reasons set forth and referenced herein, Defendants respectfully request that the Court grant their Motion to Exclude the Testimony of Bruce Rosenzweig, M.D.

Respectfully Submitted,

/s/ Christy D. Jones

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I hereby certify that on this day I electronically filed the foregoing document with the Clerk of the Court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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